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Clinical UM Guideline

Subject:	**Surgical and Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH)**		
Guideline #:	**CG-SURG-107**	**Publish Date:**	**07/01/2020**
Status:	**New**	**Last Review Date:**	**02/20/2020**

Description

This document addresses various surgical and minimally invasive procedures used in the treatment of benign prostatic hyperplasia. This document does not address the use of open prostatectomy or transurethral resection of the prostate (TURP).

Note: Please see the following related documents for additional information:

- **MED.00057 MRI Guided High Intensity Focused Ultrasound Ablation for Non-Oncologic Indications**

Clinical Indications

Medically Necessary:

The following procedures are considered medically necessary as an alternative to open prostatectomy or transurethral resection of the prostate for the treatment of benign prostatic hyperplasia:

1. **Laser-based procedures that have received U.S. Food and Drug Administration approval including, but not limited to, any of the following:**
   a. **Contact laser ablation of the prostate; or**
   b. **Holmium laser procedures, including Holmium laser ablation of the prostate, Holmium laser enucleation of the prostate, and Holmium laser resection of the prostate; or**
   c. **Interstitial laser coagulation of the prostate; or**
   d. **Photoselective laser vaporization of the prostate; or**
   e. **Transurethral ultrasound guided laser induced prostatectomy; or**

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f. **Visually guided laser ablation of the prostate, also called non-contact laser ablation of the prostate; or**

2. **Transurethral incision of the prostate in individuals with prostate volume less than 30 mL; or**
3. **Transurethral vapor resection of the prostate, also called transurethral electrovaporization of the prostate, transurethral evaporation, or transurethral vaporization of the prostate; or**
4. **Transurethral microwave thermotherapy; or**
5. **Prostatic urethral lift (for example Urolift®) in individuals with prostate volume less than 80 mL and absence of an obstructing middle lobe; or**
6. **Transurethral convective water vapor thermal ablation (for example Rezūm™) in individuals with prostate volume less than 80 mL; or**
7. **Waterjet tissue ablation (for example Aquablation®).**

Not Medically Necessary:

The following procedures are considered not medically necessary for treatment of benign prostatic hyperplasia:

1. **when above criteria are not met; or**
2. **Transurethral radiofrequency needle ablation, also called transurethral needle ablation; or**
3. **Cryosurgical ablation; or**
4. **Prostatic arterial embolization; or**
5. **Placement of temporary prostatic stents; or**
6. **Endoscopic balloon dilation of the prostatic urethra; or**
7. **Water-induced thermotherapy, also called thermourethral hot-water therapy.**

Prostatic urethral lift is considered not medically necessary when the intent is to treat symptoms of conditions other than benign prostatic hyperplasia.

Coding

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The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

~~When services are Medically Necessary:~~

CPT	
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction [when specified as prostatic arterial embolization; Note: this procedure is considered not medically necessary for BPH]
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant
52450	Transurethral incision of prostate [TUIP]
52647	Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)
52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)
52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed) [HoLRP]
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy [TUMT]

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53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy [when specified as RF needle ablation, RF TUNA, RFNA; Note: this procedure is considered not medically necessary]
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement [Note: this procedure is considered not medically necessary]
53899	Unlisted procedure, urinary system [when specified as transurethral balloon dilation of the prostatic urethra, or transurethral destruction of prostate tissue: by water-induced thermotherapy (WIT); Note: these procedure are considered not medically necessary]
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring) [Note: this procedure is considered not medically necessary for BPH]
0421T	**Transurethral waterjet ablation of prostate, including control of post-operative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)**

HCPCS	
C2596	Probe, image-guided, robotic, waterjet ablation
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

ICD-10 Procedure	
0V507ZZ	**Destruction of prostate, via natural or artificial opening**
0V508ZZ	**Destruction of prostate, via natural or artificial opening endoscopic**
XV508A4	**Destruction of prostate using robotic waterjet ablation, via natural or artificial opening endoscopic, new technology group 4**

ICD-10 Diagnosis	
N13.8	**Other obstructive and reflux uropathy**
N32.0	**Bladder neck obstruction**

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N40.0-N40.3	**Benign prostatic hyperplasia**
R33.8	**Other retention of urine**
R33.9	**Retention of urine, unspecified**
R39.11-R39.198	**Other difficulties with micturition**

~~**When services may be Medically Necessary when criteria are met:**~~

~~**CPT**~~

~~52441~~	~~Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant~~
~~52442~~	~~Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant~~
~~52450~~	~~Transurethral incision of prostate [TUIP]~~
~~53854~~	~~Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy~~

~~**HCPCS**~~

~~C9739~~	~~Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants~~
~~C9740~~	~~Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants~~

~~**ICD-10 Diagnosis**~~

~~N13.8~~	~~Other obstructive and reflux uropathy~~
~~N32.0~~	~~Bladder-neck obstruction~~
~~N40.0-N40.3~~	~~Benign prostatic hyperplasia~~
~~R33.8~~	~~Other retention of urine~~
~~R33.9~~	~~Retention of urine, unspecified~~
~~R39.11-R39.198~~	~~Other difficulties with micturition~~

~~**When services are Not Medically Necessary:**~~
~~**For the procedure codes listed above when criteria are not met.**~~

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~~**When services are also Not Medically Necessary:**~~
~~**When the code describes a procedure indicated in the Position Statement section as not medically necessary.**~~

~~CPT~~	
~~37243~~	~~Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction [when specified as prostatic arterial embolization]~~
~~53852~~	~~Transurethral destruction of prostate tissue; by radiofrequency thermotherapy [when specified as RF needle ablation, RF TUNA, RFNA]~~
~~53855~~	~~Insertion of a temporary prostatic urethral stent, including urethral measurement~~
~~53899~~	~~Unlisted procedure, urinary system [when specified as transurethral balloon dilation of the prostatic urethra, or transurethral destruction of prostate tissue: by water-induced thermotherapy (WIT)]~~
~~55873~~	~~Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)~~

~~ICD-10 Diagnosis~~	
~~N13.8~~	~~Other obstructive and reflux uropathy~~
~~N32.0~~	~~Bladder-neck obstruction~~
~~N40.0-N40.3~~	~~Benign prostatic hyperplasia~~
~~R33.8~~	~~Other retention of urine~~
~~R33.9~~	~~Retention of urine, unspecified~~
~~R39.11-R39.198~~	~~Other difficulties with micturition~~

Discussion/General Information

BPH is a disorder caused by the overgrowth of the prostate gland, which then interferes with the function of the bladder and urethra. BPH is sometimes referred to as benign prostatic hypertrophy. This condition usually results in the increased frequency of urination, frequent nighttime urination (nocturia), urinary hesitancy and urgency, and weak urinary stream. These symptoms appear slowly and progress gradually

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over years. BPH is relatively rare in younger men, affecting about 8% of men age 31 to 40 years. The incidence of BPH increases with age occurring in approximately 40% to 50% of men ages 51 to 60 years and over 80% of men older than age 80 years. Unless a man with BPH demonstrates symptoms that interfere with his quality of life and cannot be controlled with medical therapy, surgical intervention is rarely indicated.

Treatment alternatives for individuals with moderate to severe symptoms of BPH include watchful waiting, medical therapies, complementary and alternative medicines (CAM), minimally invasive therapies, and surgical therapies. The oldest form of surgical treatment includes open prostatectomy, either approaching the surgical site through the abdomen or through the perineum. However, this approach has been associated with significant morbidity and long hospital stays and is currently reserved for treating prostates greater than 100 grams.

TURP has been the preferred treatment modality for men with BPH for many years and it remains the standard against which other treatments are compared. During this procedure, surgical equipment is inserted into the urethra and guided to the area where the prostate constricts the urethral canal. Using a cutting tool, prostate tissue is excised leaving a cleared canal and a less massive prostate. Surgical treatments such as open prostatectomy and TURP may be accompanied by undesirable complications such as blood loss, need for transfusion, and absorption of irrigation fluids. Postoperative side effects may include retrograde ejaculation and incontinence.

The high rate of serious complications associated with TURP, along with the high prevalence of BPH, has encouraged development of alternative treatments. Surgical techniques have been developed using lasers, as well as minimally invasive techniques using various sources of energy including heat, microwaves, radiofrequency, and ultrasound. In these procedures, prostate tissue is removed through a heating method that destroys the desired amount of tissue that is reabsorbed by the body or expelled during urination. These treatments are intended to provide symptom relief with fewer adverse events.

Laser-Based Procedures

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~~Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.~~

~~Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.~~

Laser-based prostatectomy procedures including potassium-titanyl-phosphate photovaporization (Rusvat, 2008), holmium laser procedures (Ahyai, 2007; Wilson, 2006; Westenberg, 2004) and GreenLight laser vaporization (Al-Ansari, 2010; Mordasini, 2018), have been evaluated in comparative trials and found to compare favorably to TURP. The data in the peer-reviewed medical literature suggests that these procedures may provide improvement in BPH symptoms, voiding function, and urinary retention, in addition to comparing favorably in the long-term to TURP with equally low complication rates.

The American Urological Association (AUA) guideline on surgical management of LUTS attributed to BPH stated the following recommendation on laser enucleation (Foster, 2019):

> **Clinicians should consider holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP), depending on their expertise with either technique, as prostate size-independent suitable options for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B).**

Transurethral incision of the prostate (TUIP)

A randomized controlled trial (RCT) (Riehmann, 1995) compared TUIP and TURP in 120 individuals with bladder outlet obstruction secondary to BPH. For individuals in the study, the estimated resectable weight of the prostates was less than 20g. After a mean follow-up time of 34 months, similar improvements were seen in urinary peak flow rates in the two groups. There were no statistically significant differences between groups pre-operatively or at any post-operative follow-up in irritation, obstruction or symptom scores. Post-operative retrograde ejaculation was significantly more common in the TURP group compared with the TUIP group.

The AUA guideline on surgical management of LUTS attributed to BPH stated the following recommendation on TUIP (Foster, 2019):

> **TUIP should be offered as an option for patients with prostates ≤ 30g for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B).**

Transurethral Vaporization of the Prostate (TUVP)

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TUVP has been described as "an electrosurgical modification of the standard TURP" (Foster, 2018). A meta-analysis by Poulakis (2004) identified 20 prospective clinical trials comparing TUVP and TURP. The study found that, after 12 months, outcomes including urinary symptom scores and peak urinary flow rates were similar in the TUVP and TURP groups. TUVP was associated with a shorter operative duration and shorter hospital stay and TURP was associated with a lower rate of post-operative urinary retention and lower reoperation rates.

The AUA guideline on surgical management of LUTS attributed to BPH stated the following recommendation on TUVP (Foster, 2019):

> **Bipolar TUVP may be offered to patients for the treatment of LUTS/BPH. (Conditional Recommendation; Evidence Level: Grade B).**

Transurethral Microwave Thermotherapy (TUMT)

A Cochrane review on TUMT for treatment of BPH (Hoffman, 2012) identified 6 RCTs comparing TUMT and TURP and 8 RCTs comparing TUMT to sham treatment. Compared with sham treatment, TUMT significantly improved urinary symptom scores and peak urinary flow. In a pooled analysis the mean urinary symptom scores decreased by 65% with TUMT and 77% with TURP. Although improved in both groups, symptom improvement was significantly higher with TURP. Peak urinary flow also increased significantly more in the TURP group and there was a significantly lower risk of dysuria, urinary retention and re-treatment for BPH. However, compared with TURP, TUMT was associated with significantly decreased risks for retrograde ejaculation, hematuria, blood transfusions and treatment for strictures.

The AUA guideline on surgical management of LUTS attributed to BPH stated the following recommendation on TUMT (Foster, 2019):

> **TUMT may be offered to patients with LUTS/BPH; however, patients should be informed that surgical retreatment rates are higher compared to TURP. (Conditional Recommendation; Evidence Level: Grade C).**

Prostatic Urethral Lift (PUL) System

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The PUL system is a minimally invasive treatment for symptomatic LUTS secondary to BPH. The procedure is performed by transurethral delivery of small PUL implants to secure the prostatic lobes in an open position, thereby reducing the obstruction of the urethral lumen.

The NeoTract UroLift® System (NeoTract Inc., Pleasanton, CA) received FDA 510(k) designation (K130651) on September 13, 2013 as a de novo device. The most recent clearance was granted by the FDA in December, 2019 (K193269). Whereas the FDA originally stated that Urolift should be used in men with prostate volume >80cc and without obstructive or protruding median lobe of the prostate, the 2019 clearance stated that the system should not be used in men with prostate volume >100cc and does not mention an obstructive or protruding median lobe. No additional data were provided with the 2019 clearance. The most recent complete statement of indications for use is as follows:

> **Indications for use**
> **The Urolift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men age 45 years or older.**
>
> **Contraindications**
> **The Urolift System should not be used if the patient has:**
> - **Prostate volume of > 100 cc**
> - **A urinary tract infection**
> - **Urethra conditions that may prevent insertion of delivery system into bladder**
> - **Urinary incontinence due to incompetent sphincter**
> - **Current gross hematuria**

Regarding assessment of prostate volume, the AUA (2019) states that digital rectal examination (DRE) is unreliable for measuring prostate size. Studies have had mixed results on reliability, but there is a lack of studies demonstrating that DRE can distinguish between prostates above and below 80cc or 100cc (Bosch, 2004; Bosch, 2005; Su, 2013; Udeh, 2015; Yamamoto, 2017). The AUA (2019) states:

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Assessment of prostate size and morphology can be achieved by abdominal or transrectal ultrasonography or cystoscopy, or by cross-sectional imaging using CT or MRI. Many patients may have had such imaging as part of the workup for PSA elevation and/or prostate biopsy; therefore, any such imaging obtained in the 12 months preceding the planned surgical intervention may be utilized for size and shape assessment to verify suitability for the therapeutic alternatives under consideration since prostate growth rates are 1.6% per year on average. Imaging should provide crosssectional and sagittal imaging of sufficient resolution to calculate prostate volume and assess presence or absence of an intravesical lobe.

L.I.F.T. Trial

Roehrborn and colleagues (2013) reported initial results of the multicenter crossover RCT of the UroLift System for the treatment of LUTS secondary to BPH known as L.I.F.T. The trial included men ages 50 and older with a prostate size of 30 to 80 cubic centimeters, AUA Symptom Index (AUASI) 13 or greater and maximum flow rate 12 milliliters per second or less. Median lobe obstruction was one of the exclusion criteria. The 2-phase study included a randomized single-blinded period, starting at the time of the procedure and ending at the participant's 3-month visit, followed by a nonrandomized open-label period. After the 3-month follow-up visit, participants were participants were allowed to receive treatment with the UroLift System or any other approved BPH treatment.

A total of 206 men were randomized to PUL device (n=140) or sham treatment (n=66). The primary efficacy endpoint (intention-to-treat [ITT]) was demonstration of a reduction in AUASI at least 25% greater than that of sham treatment at 3 months post-PUL procedure. The primary safety endpoint was to demonstrate an observed rate of ≤ 10% postoperative urinary catheterization for more than 7 days. After the 3-month endpoint, 53 of 66 participants in the sham treatment group elected to undergo the PUL procedure. A total of 123 participants were included in the 12 month analysis. The primary study endpoint was met, as the mean PUL and sham AUASI was reduced by 11.1 (± 7.67) and 5.9 (± 7.66), respectively (p=0.003). PUL participants experienced AUASI reduction from 22.1 baseline to 18.0, 11.0 and 11.1 at 2 weeks, 3 months and 12 months, respectively (p<0.001). Qmax improvement increased 4.4 milliliters per second at 3 months and was sustained at 4.0 milliliters per second at 12 months (p<0.001). There was no statistical difference between groups in International Index Erectile Function (IIEF). Two serious adverse events were determined as related to the procedure (clot retention coincident with reinitiating warfarin therapy and

removal of a bladder stone at 12 months). Less serious adverse events, including postoperative dysuria, hematuria, pain/discomfort and urgency were typically mild to moderate and resolved within 2 weeks.

Additional publications on the L.I.F.T. study reported 3-year (Roehrborn, 2015) and 5-year results (Roehrborn, 2017). At 5 years, participants who underwent an additional BPH procedure, were taking a BPH medication, or deviated from study protocol were excluded from the per protocol (PP) analysis; for participants in the ITT analysis, the last value prior to study exclusion was carried forward. The ITT and PP analysis results were reported as at 5 years were: IPSS (ITT, 35%; PP, 36%), quality of life (ITT, 44%; PP, 50%), BPH-II (ITT, 47%; PP, 52%), and Qmax (ITT, 50%; PP, 44%). For 72 (51.4%) of 140 participants included in the PP analysis, change in IPSS score from baseline to 5 years was -7.56 or -35.9% (95% CI, -44.4% to -27.3%; p<0.0001). For the 140 participants included in the ITT analysis, change in IPSS score from baseline to 5 years was -7.85 or -35.0% (95% CI, -41.0 to -29.0%; p<0.0001). Of the 140 originally randomized participants, data were available for 104 (74.3%) participants at 5 years of follow-up. A total of 19 (13.6%) participants were surgically retreated for "failure to cure" following PUL at 5 years: 6 (4.3%) received additional PUL implants and 13 (9.3%) participants were treated with TURP or laser ablation (including 4 participants that exited the study). There was one adverse event occurring in 1 participant over the time period of 49 to 60 months (hematuria). Sexual function was stable over 5 years with no new sustained erectile or ejaculatory dysfunction.

BPH6 Trial

Sonksen and colleagues (2015) reported on the 12-month results of the BPH6 study, a multicenter RCT comparing PUL (n=45) to TURP (n=35) in 80 participants 50 years of age and older who were candidates for TURP. After randomization (n=91), 10 individuals (10.9%) allocated to TURP and 1 individual (1%) allocated to PUL withdrew from the study, declining the index treatment. The primary study endpoint assessed a composite of six elements (that is, symptom relief, quality of recovery, erectile function preservation, ejaculatory function preservation, continence preservation, and safety) with the overall objective of showing noninferiority of PUL to TURP for the composite endpoint at 12 months. Noninferiority was evaluated using a 1-sided lower 95% CI for the difference between PUL and TURP performance. The proportion of participants who met the BPH6 primary endpoint was 34.9% for the PUL group and 8.6% for the TURP group (noninferiority, p=0.0002; superiority, p=0.006). In the final analysis, the PUL procedure met the primary study endpoint of noninferiority and demonstrated superiority in the BPH6 primary

endpoint; however, TURP was superior in reducing IPSS reduction goal of ≥ 30% (73% vs. 91%; p=0.05) where PUL was superior for quality of recovery (p=0.008) and preservation of ejaculatory function (p<0.0001).

Gratzke and colleagues (2017) reported on 2-year outcomes of the BPH6 trial. At the 24-month follow-up, the mean difference in IPSS between PUL and TURP favored TURP (p<0.001). Subjective outcomes of participant-reported quality of life were similar between PUL (n=45) and TURP (n=35) participants at all follow-up intervals. TURP was superior with regard to Qmax scores at all study time points, while changes in health-related quality of life and BPH-II improvements were not statistically different; changes in prostate volume were not reported. Ejaculatory function bother scores did not change significantly in either treatment arm while PUL resulted in statistically significant improvement in sleep. Reoperation rates due to symptom recurrence among PUL and TURP participants did not differ significantly over the 2-year study. Six participants in the PUL arm (13.6%) and 2 participants in the TURP arm (5.7%) underwent secondary treatment for return of LUTS. The participant-reported incidence for incontinence (incontinence severity index [ISI]) change from baseline over time was statistically significant at 2 weeks and 3 months following TURP compared with PUL; however, the change over time was statistically insignificant after 6 months through 24 months of follow-up.

Several systematic reviews and meta-analyses have been published (Jones, 2016; Jung 2019; Perera, 2014). Jung, (2019) was a Cochrane review that identified two RCTs comparing PUL to sham or TURP for treatment of lower urinary tract symptoms and concluded that PUL appeared less effective than TURP at improving symptoms, similar in terms of quality of life outcomes. Jones and colleagues (2016) reviewed UroLift studies with at least 12 months of follow-up. A total of seven studies were identified with a total of 440 subjects; in the RCTs, data were only included from men in the UroLift arms. The authors reported that mean Qmax increased from 8.4 mL/s to 11.8 mL/s, mean IPSS improved from 24.1 to 14, mean quality of life improved from 4.5 to 2.3, and mean 5-item IIEF score improved from 17.7 to 18.2. The most frequent complications reported were dysuria, hematuria and pelvic pain.

Additional non-controlled studies have been published (Shah, 2018; Sievert, 2018). The Shah study found similar efficacy in men with larger (> 80 g, n=23) and smaller (< 80 g, n=51) prostates. In the Sievert study, TURP candidates were given the choice of undergoing PUL. A total of 86 individuals chose PUL, including

38 with severe BPH obstruction who would have been excluded from other studies. Within 1 month, 74 participants (86%) reported substantial improvement in symptoms. These studies are limited by the lack of a comparison or control group and lack of long-term follow-up.

The AUA guideline on surgical management of LUTS attributed to BPH stated the following recommendations on PUL (Foster, 2019):

> **Clinicians should consider PUL as an option for patients with LUTS attributed to BPH provided prostate volume < 80g and verified absence of an obstructive middle lobe; however, patients should be informed that symptom reduction and flow rate improvement is less significant compared to TURP. Patients should be informed that evidence of efficacy and retreatment rates are poorly defined. (Moderate Recommendation; Evidence Level: Grade C).**
>
> **PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of LUTS attributed to BPH (Conditional Recommendation; Evidence Level: Grade C).**

No published studies were identified that evaluated PUL for conditions other than BPH and there were no AUA recommendations on PUL for other genitourinary conditions.

Transurethral Convective Water Vapor Thermal Ablation

The Rezūm (Rezum) System (NxThera, Inc., Maple Grove, MN) received FDA 510(k) designation (K150786) on August 27, 2015 as a sterile water vapor (103ºC) system to treat BPH by delivering targeted, controlled doses of stored thermal energy (created with radiofrequency current) directly to the transition zone of the prostate gland. According to the FDA, the Rezūm System is indicated for men who are at least 50 years old with a prostate volume ≥ 30cm^3 and ≤ 80cm^3. The Rezūm System is also indicated for treating prostates with hyperplasia of the central zone and/or a median lobe.

McVary and colleagues (2016a; 2016b) reported outcomes from a multicenter RCT using transurethral prostate convective water vapor thermal energy to treat LUTS associated with BPH. A total of 197 men aged 50 years or older with an IPSS of 13 or greater, maximum flow rate of 15 ml per second or less, and prostate volume ≥30cm^3 and ≤80cm^3 were randomized to treatment with thermal therapy using the Rezūm System (n=136) and control (n=61). Thermal water vapor was injected into the transition zone and median lobe as needed. The control procedure was rigid cystoscopy with simulated active treatment sounds. The primary endpoint was a blinded comparison of reduction in IPSS at 3 months. Participants in the Rezūm group continued to be followed until 12 months after treatment. Thermal therapy and control IPSS was reported as reduced by 11.2 ± 7.6 and 4.3 ± 6.9, respectively (p<0.0001). Participants in the Rezūm group had an IPSS reduction of 22 points from baseline at 2 weeks (p=0.0006) post-treatment and by 50% or greater at 3, 6 and 12 months (p<0.0001). The peak flow rate increased by 6.2 ml per second at 3 months and was sustained throughout 12 months (p<0.0001). Adverse events were reported as mild to moderate and resolved quickly. In a subset analysis, McVary and colleagues (2016a) evaluated participant satisfaction rates in erectile and ejaculatory function post-treatment with the Rezūm System. No treatment- or device-related de novo erectile dysfunction occurred after Rezūm therapy. Ejaculatory bother score improved 31% over baseline (p=0.0011). A total of 32% of participants achieved minimal clinically important differences in erectile function scores at 3 months, and 27% at 1 year, including those with moderate to severe erectile dysfunction.

Roehrborn and colleagues (2017b) reported 2-year outcomes of the McVary plus 1-year results of a crossover trial after transurethral prostate convective water vapor thermal energy treatment with Rezūm to treat LUTS associated with BPH. After unblinding at 3 months, 53 of 61 (86.9%) control group participants who met IPSS and Qmax criteria elected and requalified for crossover to active treatment. At 3 months (n=134), 6 months (n-129), and 12 months (n=121), per protocol crossover participants treated with Rezūm reported a significant improvement over controls in IPSS and a sustained reduction from baseline to 24 months (n=106 [80.7%] participants) (-51% change; 95% CI, -57 to -45; p<0.0001). Crossover participants experienced improvement in IPSS (p=0.004), Qmax (p<0.0001), and quality of life (p=0.0024) measures after Rezūm therapy compared to after the control procedure. During the 24-month follow-up, 8 participants received secondary treatment, including open prostatectomy (n=1), a second Rezūm procedure (n=3), and TURP (n=4).

McVary and colleagues (2019) reported outcomes up to 4-years in the Rezūm-treated group from the RCT. (Blinded comparison with the control group was not available after 3 months). Of the original 135 participants in the Rezūm group at baseline, 99 (73%) had follow-up data at 3 years and 89 (66%) at 4 years. Among available participants, mean IPSS, which had been reduced by 49.9% at 3 months, was reduced by 49.7% at year 3 and 46.7% at year 4. Symptom scores also continued to be improved compared with baseline up to 4 years. No late adverse event or *de novo* erectile dysfunction were reported.

The AUA guideline on surgical management of LUTS attributed to BPH stated the following recommendations on water vapor thermal therapy (Foster, 2019):

> **Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80 g; however, patients should be counseled regarding efficacy and retreatment rates (Conditional Recommendation; Evidence Level: Grade C).**
>
> **Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function (Conditional Recommendation; Evidence Level: Grade C).**

Waterjet Tissue Ablation

Waterjet tissue ablation, also known as Aquablation®, is a robotically executed procedure to resect and remove prostate tissue using a pressurized heat-free waterjet. Aquablation is delivered with the AquaBeam® Robotic System. In December 2017, the U.S. Food and Drug Administration (FDA) granted a de novo classification to the AquaBeam system (Procept BioRobotics Corporation, Redwood Shores, CA) for resection and removal of prostate tissue in individuals with LUTS due to BPH.

One RCT has been published; this is a double-blind non-inferiority trial comparing Aquablation (n=117) to TURP (n=67) (Gilling 2018; Gilling 2019). Eligibility included age 45 to 80. The primary outcome was the noninferiority of Aquablation to TURP on 6-month mean change in IPSS. The noninferiority margin was 4.7 points on the IPSS. Baseline IPSS scores were 22.9 in the Aquablation group and 22.2 n the TURP group. At 6 months, the IPSS decreased 16.9 points in the Aquablation group and 15.1 n the TURP group, establishing non-inferiority as well as superiority. Moreover, 90% of the Aquablation group and 79% of the TURP group

had at least a 50% decrease in IPSS. Gilling 2019 reported 1-year outcomes. Mean IPSS reduction at 12 months was 15.1 in the Aquablation group and 15.1 in the TURP group, p=0.9898. Mean percent reduction in IPSS score was also the same in both groups, 67%. Mean maximum urinary flow rates and mean reduction in post-void residual volume were similar in the two groups at 12 months. The primary safety outcome was the proportion of participants at 3 months with adverse events related to the study procedure that were Clavien-Dindo grade 2 or higher or a grade 1 event resulting in permanent disability (such as incontinence or erectile dysfunction). At 3 months, the safety endpoint was significantly lower in the Aquablation group (26%) than the TURP group (42%), p=0.0149. A total of 20 grade 2 events were reported in 19 individuals undergoing Aquablation compared with 15 Grade 2 events in 11 TURP recipients. Between months 3 and 12, 12 additional adverse events deemed related to the study procedures were reported; rates were similar between groups.

A 2019 Cochrane review on Aquablation by Hwang identified only one RCT, the Gilling study described above. The authors' conclusions on the evidence were as follows:

> **Based on short-term (up to 12 months) follow-up, the effect of Aquablation on urological symptoms is probably similar to that of TURP (moderate-certainty evidence). The effect on quality of life may also be similar (low-certainty evidence). We are very uncertain whether patients undergoing Aquablation are at higher or lower risk for major adverse events (very low-certainty evidence). We are very uncertain whether Aquablation may result in little to no difference in erectile function but offer a small improvement in preservation of ejaculatory function (both very low-certainty evidence). These conclusions are based on a single study of men with a prostate volume up to 80 mL in size. Longer-term data and comparisons with other modalities appear critical to a more thorough assessment of the role of Aquablation for the treatment of LUTS in men with BPH.**

The AUA guideline on surgical management of LUTS attributed to BPH stated the following recommendation on Aquablation (Foster, 2019):

> **Aquablation may be offered to patients with LUTS attributed to BPH provided prostate volume > 30/< 80g, however, patients should be informed that long term evidence of efficacy**

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and retreatment rates, remains limited. (Conditional Recommendation; Evidence Level: Grade C).

Transurethral Radiofrequency Needle Ablation or Transurethral Needle Ablation (TUNA)

The AUA guideline (Foster, 2018) stated: "TUNA is not recommended for the treatment of LUTS attributed to BPH. (Expert Opinion)"

Cryosurgical Ablation

Cryosurgical ablation for treatment of BPH is not addressed in current AUA guidelines and no published controlled or uncontrolled studies evaluating this procedure for treating BPH were identified.

Prostatic Arterial Embolization (PAE)

PAE has been proposed as a treatment for BPH to reduce the blood supply of the prostate gland which results in some of the gland undergoing necrosis with subsequent shrinkage. The procedure is performed with the individual under local anesthetic using a percutaneous transfemoral approach. Embolization is achieved using microparticles (such as gelatin sponge, polyvinyl alcohol [PVA], and other synthetic biocompatible materials) introduced by super-selective catheterization to block small prostatic arteries. In June 2017, the U.S. FDA granted a de novo classification to the intravascular implant, Embosphere Microspheres (BioSphere Medical, S.A., France), as a class II biocompatible PAE device for use as a minimally invasive treatment for symptomatic BPH.

The published literature on PAE has been summarized in several systematic reviews and meta-analyses (Jiang, 2019; Malling, 2019; Shim, 2017). Malling (2019) reviewed controlled and uncontrolled studies on PAE for BPH that had at least 10 participants and at least 6 months of follow-up. A total of 13 studies met the review's eligibility criteria, including 2 randomized controlled trials (RCTs). One RCT (Carnevale, 2016) had only 2 participants and the other (Gao, 2014) included 114 individuals. The primary outcome of interest was mean change in the International Prostate Symptom Score (IPSS). In a pooled analysis of symptom improvement at 12 months among individuals receiving PAE, the mean reduction (indicating symptom

improvement) in IPSS was -16.2 points (95% confidence interval [CI], -18.3 to -14.0). Secondary outcomes, including quality of life and prostate volume, also improved after PAE. The meta-analysis is limited by lack of comparative analysis and the literature on PAE is limited by the small number of comparative studies.

The meta-analysis by Jiang (2019) focused on studies comparing PAE to TURP and evaluated short-term outcomes. Four studies were included in the review, the 2 RCTs mentioned above as well as two comparative observational studies. In a pooled analysis of data from tw studies, there was no significant difference in post-operative IPSS. The post-operative peak flow rate (Qmax) was significantly higher in the TURP group than the PAE group. Similarly, the post-operative prostate volume and quality of life improved significantly more in the TURP group. Data from two studies found no statistically significant differences in complications in the two groups.

The RCT by Gao (2014) included individuals with lower urinary tract symptoms (LUTS) due to BPH who had an IPSS score greater than 7, a prostate volume of 20-100 mL and peak urinary flow of less than 15 mL per second. A total of 114 individuals met the eligibility criteria and were randomized to PAE (n=57) or TURP (n=57). Participants were followed for a mean of 22.4 months. Efficacy outcomes included IPSS, quality of life, peak urinary flow and post-voiding residual urine volume. At the 1- and 3-month follow-ups, there was significantly greater improvement in these outcomes in the TURP group. At all time-points, there was significantly greater reduction in prostate volume in the TURP group. A significantly higher percentage of individuals in the PAE group had complications; most of these were minor complications. In the PAE group, there were 22 (38.6%) minor complications and 8 (14%) major complications whereas in the TURP group, there were 13 (22.8%) minor complications and 4 (7%) major complications. Technical and clinical treatment failure were included in the calculation of major complication.

A randomized non-inferiority trial was published by Abt and colleagues in 2018. The study included 103 individuals with refractory LUTS due to BPH who were randomized to undergo PAE (n=48) or TURP (n=51). Non-inferiority for the primary outcome was defined as less than a 3 point difference in IPSS improvement at 12 weeks. From baseline to 12 weeks, change in the IPSS was -9.23 points after PAE and -10.77 after TURP. Although the difference between groups was less than 3 points, the authors stated that non-inferiority could not be established "owing to the large variation among individual outcomes (95% confidence interval for mean difference−1.45 to 4.52 points". Functional outcomes at 12 weeks favored the

TURP group. The risk of one or more treatment-related adverse events was similar in the 2 groups but more individuals in the TURP group had 2 or more treatment-related adverse events.

The AUA guideline on surgical management of LUTS attributed to BPH (Foster, 2019) included an expert opinion recommendation that stated, "PAE is not recommended for the treatment of LUTS/BPH outside the context of a clinical trial."

The AUA panel stated that the overall quality of the evidence on PAE for treating BPH is low and the available studies are susceptible to selection, detection, attrition and reporting biases. They also noted "substantial heterogeneity" among the available RCTs such as different definitions of subjective response to treatment.

Unlike the AUA, the 2019 Society of Interventional Radiology (SIR) Multisociety Consensus Position Statement recommended consideration of PAE in certain circumstances. The SIR document included the following recommendations on PAE for treating BPH:

1. **PAE is an acceptable minimally invasive treatment option for appropriately selected men with BPH and moderate to severe LUTS. (Level of evidence: B; strength of recommendation: strong.)**

In other recommendations (all with level of evidence: C), the SIR guideline stated that PAE could be considered a treatment option in patients with BPH who have very large prostates (> 80 cm^3), with acute or chronic urinary retention as a method of achieving catheter independence and in those who wish to preserve erectile and/or ejaculatory function.

Temporary Prostatic Stents

A temporary prostatic stent, The Spanner™ (SRS Medical, North Billerica, MA), received premarket approval (PMA) from the FDA based on a multicenter, prospective, randomized clinical trial designed to evaluate the safety and effectiveness of The Spanner to manage LUTS and bladder emptying following TUMT treatment after an initial period of catheterization. Based on the study results, the FDA indicates "The device is intended for temporary use (up to 30 days) to maintain urine flow and allow voluntary

urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization."

An RCT evaluating The Spanner (Dineen, 2008; Shore, 2007) included 186 individuals who were 45 years of age and older. A total of 100 subjects who received The Spanner and 86 subjects in a control group were studied for changes in IPSS, PVR, and adverse events. Both groups were evaluated at 1-, 2-, and 4-week intervals during The Spanner indwelling period and at 2 and 4 weeks after The Spanner removal. Beginning with preoperative IPSS scores of approximately 22 points, The Spanner group score decreased by 7.28 points compared to 4.42 points in the control group, a difference of 2.86 points (p=0.019). However, although evaluation at the 1-week interval revealed a significant difference of 3 points between the groups (p=0.047), at 2 weeks and at subsequent visits, this was no longer the case (p=0.084 at 2 weeks). Mean PVR was significantly less in The Spanner group compared to controls up to 4 weeks following randomization, with the mean decrease from pre-insertion baseline being 6.5 mls in The Spanner group versus a 28.5 ml increase in the control group. However, after 4 weeks there was no significant difference in PVR between the groups. The most notable limitation of this study is the lack of long-term follow-up, as uroflowmetry, PVR, and IPSS data was only collected up to 1 week following stent removal; therefore, the durability of the results are not evident.

The FDA summary reported the majority of adverse events, greater than 75% for both groups, occurred during weeks 1 to 4 following insertion. Adverse events also occurred following removal of the device and included bleeding/hematuria, urinary frequency/retention/urgency, perineal pain, and symptomatic urinary tract infection. There were 385 adverse events reported by 99 subjects in The Spanner group and 273 adverse events reported by the 80 control group subjects. The study results are limited in demonstrating meaningful improvement in clinical outcomes in the group that received the temporary prostatic stent compared to the subjects studied who had a successful voiding trial after BPH surgery. The clinical significance of decreased IPSS scores at 1 week only with a difference of 3 points at that visit is questionable as is the difference in PVR noted up to 4 weeks, in the absence of increased urinary tract infections or other PVR-related adverse effects in the control group compared to The Spanner group. On the other hand, perineal pain was noted to occur more frequently in The Spanner treated group.

Endoscopic Balloon Dilation of the Prostatic Urethra

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Endoscopic balloon dilation for treatment of BPH involves the insertion of a balloon catheter tip through the urethra into the prostatic channel where it is inflated to stretch the urethra narrowed by the prostate. Based on the research, endoscopic balloon dilation has been inadequately studied with limited controlled trials, few long-term studies, and "a fallout in enthusiasm" for this treatment (Lukkarinen, 1999). The 4th International Consultation on BPH rated balloon dilation as an unacceptable treatment option (Denis, 1998).

Endoscopic balloon dilation is not mentioned in the 2019 AUA guideline.

Water-induced Thermotherapy (WIT)

No published RCTs have addressed WIT. WIT has only been evaluated in cases studies; these have found that the treatment can relieve the symptoms of BPH but lack control or comparison groups (Breda, 2002; Muschter, 2000).

The 2019 AUA guideline does not address WIT.

Definitions

Ablation: To surgically remove or excise a body part.

American Urological Association Symptom Index (AUA SI): The seven questions in the AUA SI are as follows:

1. **During the last month or so, how often have you had a sensation of not emptying your bladder completely after you finish urinating?**
2. **During the last month or so, how often have you had to urinate again less than 2 hours after you finished urinating?**
3. **During the last month or so, how often have you stopped and started again several times when you urinated?**

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4. During the last month or so, how often have you found it difficult to postpone urinating?
5. During the last month or so, how often have you had a weak urinary stream?
6. During the last month or so, how often have you had to push or strain to begin urination?
7. During the last month or so, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?

The symptom score is the sum of the responses to all of the questions. The response to each question varies from 0 to 5, with a potential total score ranging from 0 to 35. According to the validation study reported by Barry and colleagues (2017), a score of 8-19 is considered to indicate moderate symptoms and a score of 20 or more is considered to indicate severe symptoms.

Benign prostate hyperplasia (BPH): A condition that causes an increase in the size of the prostate gland in men, commonly causing difficulty in urination; also referred to as benign prostatic hypertrophy.

Benign Prostatic Hyperplasia Impact Index (BPH-II): A self-administered, 4-item questionnaire with a final score range of "0" (best) to "13" (worst), used to measure the effect of urinary symptoms on health domains.

Contact laser ablation of the prostate (CLAP): A procedure where the tip of an Nd:YAG laser is placed in direct contact with prostate tissue, vaporizing it.

Cryosurgical: A treatment performed with an instrument that freezes and destroys abnormal tissue.

Holmium laser procedures of the prostate (HoLAP, HoLEP, HoLRP): Procedures that use a holmium laser fiber and specially adapted resectoscope to either ablate (HoLAP), enucleate (HoLEP), or resect (HoLRP) prostate tissue.

Hyperplasia: Enlargement of an organ or tissue because of an increase in the number of cells in that organ or tissue.

Hypertrophy: Enlargement or overgrowth of an organ or tissue due to an increase in size of its cells, rather than the number.

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International Prostate Symptom Score (IPSS): An eight question, self-administered tool (seven symptom questions plus one quality of life question) used to screen for BPH-related symptoms.

Laser prostatectomy: A procedure that uses laser-generated heat to remove prostate tissue obstructing the urethra.

Lower urinary tract symptoms (LUTS): The chief complaint associated with BPH, typified by urinary frequency, urgency, nocturia, decreased and intermittent force of stream and the sensation of incomplete bladder emptying.

Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD): A self-administered questionnaire consisting of a 4-item scale measuring ejaculatory function.

Prostatic urethral lift (PUL): A permanently implanted lift device intended to hold the lateral prostatic lobes apart and create a passage through an obstructed prostatic urethra to improve the voiding channel.

Sexual Health Inventory for Men (SHIM): A self-administered, 5-item questionnaire consisting of a final score range of "1" (worst symptoms) to "25" (fewest symptoms) measuring erectile function.

Stent: A tube made of metal or plastic that is inserted into a vessel or passage to keep the lumen open and prevent closure due to a stricture or external compression.

Transurethral: A surgical approach to prostate surgery that involves the insertion of surgical tools through the urethra instead of through an incision in the skin.

Transuretheral incision of the prostate (TUIP): A surgical procedure involving one or more lengthwise incisions in the prostate near the bladder, which opens the bladder neck and prostate to reduce pressure on the urethra; usually limited to treating smaller prostate glands (equal to or less than 30 grams).

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Transurethral microwave thermotherapy (TUMT): A minimally invasive treatment that uses microwave energy to heat and shrink the prostate to provide relief of urinary obstruction due to BPH.

Transurethral radiofrequency needle ablation (TUNA, RFNA): A non-surgical procedure in which low-level radiofrequency energy is delivered through a needle to a small area of the prostate, with the goal of relieving symptoms associated with BPH.

Transurethral vaporization of the prostate (TUVP): A surgical procedure where prostate tissue is vaporized using a grooved or spiked rollerball or thicker band-loop electrode, considered a modification of a transurethral resection of the prostate (TURP); also referred to as transurethral electrovaporization of the prostate (TUEVP, TUVAP, TUEVAP), transurethral evaporation (TUEP), or transurethral vapor resection of the prostate (TUVRP).

Vaporization procedures of the prostate: Procedures that use electrical energy to vaporize prostate tissues, differing from TURP and each other according to the type of electrode used and the magnitude of electrical energy applied. Prostate tissue is vaporized, resected into pieces or "chips," or coagulated.

Visually guided laser ablation of the prostate (VLAP): A non-contact laser ablation procedure where a Nd:YAG laser is held a short distance (two millimeters) from the prostate tissue, destroying it by coagulation and allowing it to slough away over several weeks; reserved for treating small or moderately small prostates (less than 80 grams).

Water-induced thermotherapy (WIT): A minimally invasive approach to the treatment of BPH involving the use of very hot water to shrink prostate tissue; also referred to as thermourethral hot water therapy.

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symptoms attributed to benign prostatic hyperplasia: From the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, Société Française de Radiologie, and the British Society of Interventional Radiology: Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology. J Vasc Interv Radiol. 2019; 30(5):627-637.

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Government Agency, Medical Society, and Other Authoritative Publications:

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2. **Centers for Medicare and Medicaid Services (CMS). National Coverage Determination for Laser Procedures. NCD #140.5. Effective May 1, 1997. Available at: http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=140.5&ncd_version=1&basket=ncd%3A140%2E5%3A1%3ALaser+Procedures. Accessed on January 15, 2020.**
3. **Denis L, McConnell J, Khoury S, et al. Recommendations of the International Scientific Committee: the evaluation and treatment of lower urinary tract symptoms (LUTS) suggestive of benign prostatic obstruction. Proceedings of the Fourth International Consultation on Benign Prostatic Hyperplasia. United Kingdom: Health Publications, Ltd. 1998; 669-684.**
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Websites for Additional Information

1. **National Cancer Institute. Understanding Prostate Changes: A Health Guide for Men. Available at: https://www.cancer.gov/types/prostate/understanding-prostate-changes. Accessed on January 16, 2020.**
2. **National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC, NIH). Prostate enlargement: benign prostatic hyperplasia. Available at: https://www.niddk.nih.gov/health-information/urologic-diseases/prostate-problems/prostate-enlargement-benign-prostatic-hyperplasia. Accessed on January 16, 2020.**

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	02/20/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of SURG.00028 to new clinical utilization management guideline document with the same title. Added examples of technologies for prostatic urethral lift, transurethral convective water vapor thermal ablation and waterjet tissue ablation. Added statement that prostatic urethral lift is considered not medically

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necessary when the intent is to treat symptoms of conditions other than benign prostatic hyperplasia.

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